K070083

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510(k) SUMMARY

MAY 15 2007

A. Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 (215) 256-4201 Telephone (215) 256-9191 Fax
Contact:	Jean Callow, Regulatory Specialist
Date Prepared:	December 29, 2006

B. Trade Names: Not assigned at time of submission

Common Name:	Power Injectable, Implantable, Infusion Port
Classification Name:	Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
	Long Term
Classification:	LJT
Classification Advisory Committee:	General Hospital
C.F.R. Section:	880.5965
Device Classification:	II

C. Predicate Devices:

K864349 Mediport II Single Lum/Port Vascular Access Port (M.R.I)., Bard Access Systems

K060812, PowerPort Implanted Titanium Port with 8Fr. ChronoFlex® Catheter., Bard Access Systems

D. Device Description:

The Power Injectable, Implantable Infusion Port is a subcutaneously implantable single fluid reservoir port offered with a choice of a silicone (9.6F) or polyurethane (8F) catheter either pre-attached by the manufacturer or attachable for application by the inserting physician. Placement of the port is determined by the inserting physician based on patient anatomy and medical judgment. The port can be anchored with sutures in the port pocket for secure seating. The catheter lock provides securement of the catheter to the port stem. The port is accessed by inserting a non-coring needle through the skin into the self-sealing septum.

The base of the port is printed with the letters "CT" in reverse with radiopaque ink to signify that it can be used for power injection on contrast agents (orientation will appear correct under x-ray). Lot numbers are laser etched into the base of the port. The assembly is over molded with an optically clear silicone to prevent tissue in growth to the suture holes that are easily accessed through the silicone. The rigid top half of the port centers the silicone septum and aids in locating the implanted device under the skin.

Power injection of contrast media, can be safely administered with a 19 or 20 gauge power injectable infusion non-corning needle at a maximum recommended infusion rate of 5 ml/s.

The implantable infusion port is packaged with the necessary accessories to facilitate catheter insertion.

The body of the port is manufactured with a polysulfone housing as the predicate device cleared under K864349. The addition of power injection capability is comparable to the currently marketed PowerPort cleared under K060812.

E. Intended Use:

The Power Injectable Implantable Infusion Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples.

When used with a power injectable needle, the power injectable infusion port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s with a 19 or 20 gauge non-coring power injectable needle.

F. Comparison to Predicate Devices:

The Power Injectable, Implantable Infusion Port is substantially equivalent to the predicate devices in terms of intended use, insertion method, anatomical location, design, performance, materials, labeling and method of sterilization.

G. Safety and Effectiveness / Performance Data:

In vitro testing was performed on the Power Injectable, Implantable Infusion Port to assure reliable design and performance in accordance with the FDA's "Guidance on 510(k) Submissions for Implanted Infusion Ports" dated October 1990. Verification testing and performance testing performed according to the referenced standards as well as in accordance with in-house protocols.

Clinical studies were not deemed necessary since in vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to legally marketed predicate devices. This device presents no known additional risks to the patient that are not well documented and for which there is already a prescribed therapy.

Biocompatibility testing on the Power Injectable, Implantable Infusion Port demonstrates that the materials used meet the requirements of ISO 10993 for a permanent implantable tissue and blood contact device. All materials used in this product are the same or similar to other vascular access products and present no unusual or unacceptable risk to the patient.

H. Conclusion:

Performance data indicated the performance and materials of the Power Injectable Implanted Infusion Port is equivalent to the claims of the currently marketed Mediport II

Single Lum/Port Vascular Access Port (M.R.I) and PowerPort Implanted Titanium Port with 8Fr. ChronoFlex® Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2007

Ms. Jean Callow
Regulatory Specialist
MedComp
1499 Delp Drive
Harleysville, Pennsylvanian 19438

Re: K070003
Trade/Device Name: The Power Injectable Implantable Infusion Port
Regulation Number: 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: May 8, 2007
Received: May 9, 2007

Dear Ms. Callow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070003
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Indications for Use

510(k) Number (if known): _____

Device Name: ___THE POWER INJECTABLE IMPLANTABLE INFUSION PORT___

Indications for Use:

THE POWER INJECTABLE IMPLANTABLE INFUSION PORT IS INDICATED FOR PATIENT THERAPIES REQUIRING REPEATED ACCESS TO THE VASCULAR SYSTEM. THE PORT SYSTEM CAN BE USED FOR INFUSION OF MEDICATIONS, I.V. FLUIDS, PARENTERAL NUTRITION SOLUTIONS, BLOOD PRODUCTS AND FOR THE WITHDRAWAL OF BLOOD SAMPLES.

WHEN USED WITH A POWER INJECTABLE NEEDLE, THE POWER INJECTABLE INFUSION PORT IS INDICATED FOR POWER INJECTION OF CONTRAST MEDIA. FOR POWER INJECTION OF CONTRAST MEDIA, THE MAXIMUM RECOMMENDED INFUSION RATE IS 5 ML/S WITH A 19 OR 20 GAUGE NON-CORING POWER INJECTABLE NEEDLE.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...ion Sign-Off)
...sion of Anesthesiology, General Hospital,
...ection Control, Dental Devices
...0(k) Number: K070003

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